(d)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established in §20.21 that such records shall be made available to all members of the public.

(e) For purposes of this section, the term ''official of a foreign government agency'' includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. For such officials, the statement and commitment required by paragraph (c)(1)(i) of this section shall be provided on behalf of both the organization and the individual.

[42 FR 15616, Mar. 22, 1977, as amended at 58 FR 61603, Nov. 19, 1993; 60 FR 63382, Dec. 8, 1995; 65 FR 11888, Mar. 7, 2000]

§ 20.90 Disclosure to contractors.

(a) Data and information otherwise exempt from public disclosure may be disclosed to contractors with the Food and Drug Administration and their employees for use only in their work for the Food and Drug Administration. Contractors and their employees are thereafter subject to the same legal restrictions and penalties with respect to the disclosure of such data and information as Food and Drug Administration employees.

(b) A written agreement between the Food and Drug Administration and any contractor shall be entered into before data and information otherwise exempt from public disclosure may be disclosed to the contractor. The contractor shall agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The written agreement shall include, where appropriate, provisions establishing:

(1) Restrictions on access to the data and information by the contractor, its employees, or other persons;

(2) Physical storage requirements;

(3) Requirements for the handling and accountability of the data and information by the contractor and its employees;

(4) Limitations on reproduction, transmission, and disclosure of the data and information;

(5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;

(6) Procedures to be followed when the contractor employs time-shared computer operations;

(7) Methods of destroying source documents or related waste material; and

(8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross-reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in subpart D of this part and the limitations on exemptions established in subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 20.60 and 20.80. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in subpart D of this part except as provided by the limitations on exemptions specified in subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

(1) Section 305 hearing records, in § 7.87(c) of this chapter.

(2) Flavor ingredient records and notes, in § 101.22(i)(4)(iv) of this chapter.

(3) Environmental assessments; finding of no significant impact, in § 25.51 of this chapter, or draft and final environmental impact statements, in § 25.52 of this chapter.

(4) Color additive petitions, in § 71.15 of this chapter.

(5) Food standard temporary permits, in § 130.17(k) of this chapter.

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 108.35(l) of this chapter.

(7) Food additive petitions, in §§ 171.1(h) and 571.1(h) of this chapter.

(8) Action levels for natural and unavoidable defects in food for human use, in § 110.110(e) of this chapter.

(9) Drug establishment registrations and drug listings, in § 207.37 of this chapter.

(10) Investigational new animal drug notices, in § 514.12 of this chapter.

(11) New animal drug application files, in § 514.11 of this chapter.

(12) Investigational new animal drug notice and a new animal drug application file for an antibiotic drug, in § 514.10 of this chapter.

(13) Methadone patient records, in § 291.505(g) of this chapter.

(14) Investigational new drug notice, in § 312.130 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.430 of this chapter.

(16) Master file for a new drug application, in § 312.420 of this chapter.

(17) New drug application file, in § 314.430 of this chapter.

(18) Data and information submitted for in vitro diagnostic products, in § 809.4 of this chapter.

(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.